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Inventor(s): Doyle et al.
S.N.: 09/607,602
Filed: 6/30/00
Case: 8141

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Case Docket No. 8141

In the Application of
Inventor(s): MATTHEW JOSEPH DOYLE, ET AL.
Serial No.: 09/607,602 Group Art Unit: 1644
Date Filed: June 30, 2000 Examiner: A. DeCloux
Title: PROMOTING WHOLE BODY HEALTH Confirmation No. 8543

RESPONSE UNDER § 1.111

ASSISTANT COMMISSIONER FOR PATENTS
Washington D.C. 20231

Dear Sir:

In response to the final Office Action dated October 21, 2002 and having a shortened statutory period for reply of three months thereafter, please consider the remarks herein. This response is being filed within two months of the mailing date of the final Office Action and no extension fees are believed to be due.

REMARKS

Method Claims 2-4 and 7 remain pending in the application. Claims drawn to nonelected subject matter that have been withdrawn for consideration at this time will be pursued in a divisional application.

The present invention as now claimed is specific to a method for promoting whole body health or systemic health. The method involves topically administering a composition comprising a host response modulating agent, specifically a H2 antagonist, to the oral cavity as opposed to systemic administration, which would be the normal route to provide a systemic benefit. The present claims are based on Applicants' discovery of a new use for a method of topical treatment of the oral cavity. Specifically Applicants have discovered that topical administration to the oral cavity of compositions comprising a host response modulating agent, specifically a H2 antagonist, is beneficial in promoting systemic health in addition to treating or preventing oral cavity conditions such as periodontitis and gingivitis. In particular, the present method effectively decreases etiologic factors that contribute to development of certain systemic diseases such as heart disease. By decreasing the etiologic factors for systemic disease, the risk of developing such a disease is also decreased leading to better overall health for the subject.

Claims Rejection Under 35 USC § 102(b)

The Examiner has maintained the rejection of Claims 2-4 and 7 under 35 USC § 102(b) as being anticipated by Pan et al. (WO 97/16159) and by commonly assigned Singer et al. (US 5,364,616). Claim 2 is rejected under 35 USC § 102(b) as anticipated by Tsujita et al. (JP 04/089428). The Examiner contends that because the process steps are not novel, the results of the process steps are inherent.

Applicants respectfully traverse the Examiner's rejection of the claims in view of the Pan et al. (WO 97/16159), Singer et al. (US 5,364,616) and Tsujita et al. (JP 04/089428) references.

Firstly, Applicants will address the Examiner's point that the present claimed "new use" of promoting whole body health is simply a statement purpose and intended result and is therefore not considered limiting. The Examiner cites *Bristol-Myers Squibb v. Ben Venue Laboratories 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001)* for the proposition that:

> *[The] preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of process should be considered limiting because it distinguishes process over prior art.*

The present case is distinguishable over *Bristal* in that the present "use", namely "promoting whole body health", is a "new use" or NOT KNOWN or suggested by the art. By contrast, the "use" in *Bristol*, i.e., "treating cancer by administering paclitaxel" is the same "use" as disclosed in the applied prior art (Kris). Indeed the *Bristol* Court conceded that new uses of known process may be patentable.

> *Bristol is correct that new uses of known processes may be patentable. See 35 U.S.C. § 101 (1994) (Whoever invents or discovers any new and useful process... may obtain a patent therefore."); 35 U.S.C. § 100(b) (1994) ("The term "process" means process, art or method and includes a new use of a known process, machine, manufacture, composition of matter, or material.").*

However, the Court continues, "*the claimed process here is NOT directed to a new use; it is the same use, and it consists of the same steps as described by Kris* [the prior art reference].... *Bristol has done no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients As in May, the purpose — treating cancer— is no different from the purpose disclosed by Kris.*" [*Bristol* at 1377].

Turning to the claims of the present invention, Applicants assert that the art fails to teach or suggest the treatment of whole body or systemic health. The present use --promoting whole body health-- is distinguishable over *Bristol* in that the use is NOT disclosed in the prior art, and is therefore a "new use". In contrast to the facts of *Bristol*, Applicants do NOT attempt to claim "newly discovered results of a known process directed to the same purpose" but rather, claim a novel and unobvious ***process*** by virtue of a "new use" or a different purpose. Clearly, promoting systemic or whole body health is a different use than treating local or nonsystemic conditions, i.e., gingivitis or periodontitis, as disclosed by the applied references. There is no teaching whatsoever in any of the cited references of directing topical

administration of a composition comprising a host response modulating agent, specifically a H2 antagonist, for the purpose of promoting systemic or whole body health. Therefore, Applicants assert that the present claimed method of promoting whole body health is patentable in accordance to well-established Federal Circuit jurisprudence.

The present claims define a method for a "new use", i.e., promoting whole body health, by topical administration to the oral cavity of a composition comprising a H2 antagonist. By the present claimed method, spread into the bloodstream and other parts of the body of pathogenic oral bacteria and associated harmful substances including toxins and endotoxins is prevented or minimized. The result is a decrease in the causative factors for certain diseases and a corresponding decrease in the risk of development of these systemic diseases, such as heart disease. Thus, the present claims are directed to a new use for a method that traditionally has been used solely for locally treating or preventing bacteria-mediated diseases and conditions of the oral cavity.

Applicants respectfully submit that the present method claims directed to a new use of topical administration a H2 antagonist are novel and unobvious in view of the cited references. There is no disclosure nor any suggestion in any of the citations with regard to whole body or systemic health, much less that the present H2 antagonist containing compositions administered topically to the oral cavity would promote whole body health by decreasing causative or risk factors that are involved in the development of certain systemic diseases. The benefits to systemic health when the method of treatment is by topical administration as opposed to systemic administration have not been appreciated in the applied citations nor in any other prior disclosure.

Applicants again direct the Examiner's attention to the submitted declaration by present inventor Robert E. Singer, Jr., that presented findings relevant to the mechanism of action of topical H2 antagonists. The present claims are based on the discovery that topical treatment of the oral tissues with H2 antagonists serves to increase the gingival barrier function of the periodontal tissues. From a series of studies conducted under Mr. Singer's direction, it has been demonstrated that topical H2 antagonists (1) increase gingival crevicular polymorphonuclear (PMN) function for the phagocytosis and killing of bacterial pathogens; (2) elevate the levels of gingival crevicular antibodies during experimental periodontitis; and (3) increase the levels of gingival crevicular fluid (GCF) IgA, a marker for the protective gingival tissue response. Taken together, these findings indicate that H2 antagonists enhance the function of key mechanisms of the gingival barrier function.

From these new findings, it is evident that the topical application of H2 antagonists to oral tissues represents a unique and unanticipated approach to increasing the barrier function of periodontal tissues. The abilility of H2 antagonists to increase the natural barrier function of gingival tissues is an extremely important benefit in as much as this unique mechanism of action enables providing not only a benefit vs. periodontal disease but unexpectedly also represents an effective approach to preventing oral pathogens and their products from entering into either the gingival tissues or the systemic circulation. Consequently, topical application of H2 antagonists affords unanticipated benefits for preventing oral pathogens from

prompting the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.

Applicants also traverse the Examiner's contention that the present method claims are not patentable because the results of the claimed methods, i.e., "whole body health benefits", are inherent.

The present method claims fall within the definition under 35 U.S.C. § 100(b) for a patentable "process" which means process, art or method, and includes **a new use of a known process, machine, manufacture, composition or matter or material.** (emphasis added), as acknowledged by the Court in *Bristol-Myers Squibb v. Ben Venue Laboratories*. See also *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir.), which found that Howes' claim to a method which makes possible the faithful transfer of color art work to fabric by means of treated heat transfer paper was patentable because Howes created a *new use of a known process*. Similarly, *claims drawn to a method for using either an old or "obvious" composition, wherein the method has unobvious beneficial or useful effects, have been found patentable even though the composition itself could not be patented.* [See *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977); *In re Legator*, 53 CCPA, 729, 352 F.2d 377 (1965); *Joseph Bancroft & Sons Co. v. Watson*, 170 F. Supp. 78 (D.D.C. 1959), 120 USPQ 265]

Applicants respectfully submit that the present claimed methods involving topically administering a composition comprising a H2 antagonist have new and unobvious beneficial effects, and are therefore patentable as a new use of a process even if such process were known. The benefits to systemic health when the method of treatment is by topical administration of the present compositions and not by systemic administration have not been appreciated in any prior disclosure.

Applicants further submit that the issue of inherency, which the Examiner has used to make the rejection is untenable in this instance, wherein the "new use" of promoting whole body or systemic health via a method that involves topical administration as opposed to systemic administration is totally unappreciated in the prior art. The Examiner's attention is respectfully directed to the case of *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977), wherein the claimed method of curbing appetite by administering certain adamantane compounds was found to be patentable over prior references that disclosed administering similar compounds to achieve antiviral effects in amounts encompassing the amounts intended and claimed by *Shetty* for appetite suppression. The PTO had held that the compounds used by *Shetty* are obvious over the references and the benefit of curbing appetite claimed by *Shetty* is inherent. The CCPA rejected the PTO's position and reversed the rejection of *Shetty's* method claims for curbing appetite, stating the following:

> *We cannot accept this conclusion. The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant's "amount effective to curb appetite" corresponds to or inheres in Narayanan's amount "to combat microbial infestation" does not persuade us of the obviousness of appellant's method. As this court said in In re Naylor, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966):*

[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.

Applicants further direct the Examiner's attention to the directive under MPEP 2112 and 2131.02 Section III, that the Examiner must provide rationale or evidence to show inherency. As stated therein:

"In relying upon the theory of inherency, the examiner must provide a basis in fact and or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish that result or characteristic."

There must be evidence to support the Examiner's allegation that a characteristic not disclosed in cited reference is inherent. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

As in the *Shetty* case, the Examiner has not provided any evidence whatsoever to establish that one of ordinary skill in the art would appreciate or recognize the beneficial effects, i.e., promoting systemic or whole body health of the present claimed method. There is no disclosure or suggestion in any of the citations that a method involving topical administration of a composition containing the recited H2 antagonists as opposed to systemic administration would be useful in promoting systemic health. In fact, all of the disclosure in the cited art relate to the use of H2 antagonist compounds to treat periodonditis or gingivitis, which are local or non-systemic conditons. Accordingly, the rejection of the claims under §102(b) over the citations cannot stand.

Finally, Applicants submit that it is well established under US patent law that a second medicinal use of a substance already suggested or known to be useful in treating a human or animal disease is patentable as a method of use. While there are numerous examples, Applicants cite the granting of US 6,100,270 (to Pfizer) with method claims for a second medicinal use, i.e., treating male erectile dysfunction, for sildenafil compositions, which have previously been patented for the treatment of many conditions including angina, hypertension and congestive heart failure (US 5,250,534 and US 5,346,901). The method in this case involves the same method of oral administration of the compositions containing the active sildenafil. The second or new use is the basis for patentability of the method.

As another example, claims to methods of treating male pattern baldness using minoxidil by topical administration were patentable as a second use (US 4,139,619 and US 4,596,812), even if minoxidil compositions had already been disclosed and patented for treating hypertension (US 3,461,461 and US 3,644,364). Claims to a process for obtaining increased meat, milk, egg or wool production in healthy animals comprising the administration of a minoxidil composition to a healthy animal were also allowed (US 4,393,065). Further, claims to a method of topically administering minoxidil for enhancing the growth

of unguis (the horny cutaneous plate on the dorsal surface of the distal end of the terminal phalanx of a finger or toe, i.e., fingernail or toenail) in animals, including humans were patentable (US 4,927,626). In this instance, method claims of topical administration of minoxidil for yet a new use, i.e., enhancing the growth of unguis, were patentable over prior use for growing hair. In this case, it is the same method with the same process steps of topical administration, but found patentable by virtue of the new use.

Applicants respectfully submit the present method claims are likewise directed to a new or second use --promoting systemic or whole body health-- by topical administration of H2 antagonist compounds and are therefore patentable in accordance with established US patent law and practice.

CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of the claims rejections under §102(b) and allowance of all application claims.

Respectfully submitted,

Matthew Joseph Doyle, et al.

By Emelyn L. Hiland

Emelyn L. Hiland
Agent for Applicants
Registration No. 41,501
(513) 622-3236

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The Procter & Gamble Company
Health Care Research Center (Box 1050)
P.O. Box 8006
Mason, OH 45040-8006
8141resp